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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,132	12/06/2006	Susanne Kartin Pedersen	133119.00501	5551

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EXAMINER	
GRASER, JENNIFER E	
ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
03/25/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,132	PEDERSEN ET AL.	
	Examiner	Art Unit	
	Jennifer E. Graser	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *See Continuation Sheet* is/are rejected.

7)☒ Claim(s) *43* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 December 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/28/09, 6/26/08, 12/6/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1-3,11,14,17,20-26,37,38,43,65,66,68,95,120,121,123,126,167-171,173,175,178 and 199-203.

Continuation of Disposition of Claims: Claims rejected are 1-3,11,14,17,20-26,37,38,43,65,66,68,95,120,121,123,126,167-171,173,175,178 and 199-203.

DETAILED ACTION

Claims 1-3, 11, 14, 17, 20-26, 37, 38, 43, 65, 66, 68, 95, 120, 121, 123, 126, 167-171, 173, 175, 178, and 199-203 are currently pending.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 11, 14, 17, 20, 21, 23-25, 37, 38, 43, 65, 66, 68, 95, 120, 121, 123, 126, 167-171, 173, 175, 178, and 199-203 are rejected under 35 U.S.C. 102(b) as being anticipated by (US 6,245,331).

The reference teaches a method for the early detection of mycobacterial disease. Column 21, from line 8, describes a method for identifying and isolating early Mycobacterial antigens. This involves immunocapture using an adsorbed patient serum. Columns 22, from line 31 on, describes the detection of immune complexes containing early Mycobacterium antigens suggesting that it is known to isolate complexes which can then be dissociated. See columns 17-18 for discussion of preferred immunoassays, such as ELISA and EIA. Columns 19-20 teach that direct and indirect agglutination assays may also be used. See column 21, lines 9-37 and column 22, lines 31-45.

3. Claims 1-3, 11, 14, 17, 20, 21, 26, 37, 38, 167-171, and 199-203 are rejected under 35 U.S.C. 102(b) as being anticipated by (US 5,116,766).

The reference relates to immune complex isolation and methods for diagnosing diseases. See abstract. Column 1 of the patent teaches that it was known to isolate circulating immune complexes from sera by contacting the sera with a component that binds to the immune complexes and may be removed with them. A reagent RhC is used to precipitate the immune complexes from serum. The immune complex with RhC can then be immobilized on a protein A column. The complexes are then eluted using glycine. The antigens are separated by SDS-PAGE electrophoresis and an antigen 'profile' may be generated. See "isolation of IC [Immune Complexes] bridging columns 9-10. See column 7, line 59-column 8, line 16 and Example 2.

4. Claims 1-3, 11, 14, 17, 20-26, 37, 38, 43, 65, 66, 68, 167-171, 173, 175, 178, and 199-203 are rejected under 35 U.S.C. 102(b) as being anticipated by (US 5,923,705).

The reference teaches a method for the identification and isolation of Pasteurella haemolytica antigens. This may be achieved through an immunoaffinity column which utilizes immune sera from pasteurellosis-infected cattle to selectively purify antigenic peptides. See columns 3-4 which teach the use of immunoblotting, RIA, ELISA, etc..

5. Claims 1-3, 11, 14, 17, 20, 21, 23-26, 37, 38, 43, 65, 66, 68, 167-171, 173, 175, 178, and 199-203 are rejected under 35 U.S.C. 102(b) as being anticipated by (US 6,416,962).

This reference teaches a method of identifying a Mycobacterium species responsible for a mycobacterial infection in a human or animal. The method involves exposing the antibodies from the serum of an infected individual to an antigenic

preparation and thereby identifying antigens. See abstract. The references teaches that each mycobacterial infection generates its own specific antibody response to anumber of specified antigens. It has been found that the sera of individuals which are infected with different Mycobacterium species cause different and distinguishing patterns on immunoblots of mycobacterial antigens. See column 2, lines 30-45 and columns 2-3.

6. Claims 1-3, 11, 14, 17, 37, 38, 43, 65, 167-171, 173, 175, 178, and 199-203 are rejected under 35 U.S.C. 102(b) as being anticipated by (WO 1999/00671).

The reference teaches a method for the identification of cellular protein antigens of patients with cancer which involves the use of patient derived sera. The antigen-containing protein mixture is separated by 2D electorphoresis. The proteins which are bound are identified as proteins to which a subject with cancer produces autoantibodies (i.e,. they are immunogenic). The separated proteins may be used for immunization or for immunoassays.

7. Claims 1-3, 11, 14, 20, 21, 37, 38, 43, 65, 66, 167-171, 173, 175, 178, and 199-203 are rejected under 35 U.S.C. 102(b) as being anticipated by (US Patent No. 5,670,312).

The method teaches a method for isolating peptides and/or other molecules which specifically bind to antibodies in sera. The antibodies are immobilized on a solid support and a library of peptides is brought into contact with the antibodies. Any non-disease specific antibodies from a second patient sample will not bind the peptides isolated by this method; therefore only disease specific antibodies are identified.

8. Claims 1-3, 11, 14, 17, 20, 21, 23-26, 43, 65, 66, 68, 95,167-171, 173, 175, 178, and 199-203 are rejected under 35 U.S.C. 102(b) as being anticipated by Ranadive et al (Clin Exp. Immuno. 1986. 64:277-284).

Ranadive et al describe a study of antigens from Mycobacterium tuberculosis that cause a humoral response using immunoaffinity, SDS-PAGE and autoradiography. Ranadive teach that labeled M.tuberculosis antigens were immunoprecipitated with tuberculosis patients' sera and analyzed by SDS-PAGE. A group of four polypeptides were identified. Antibody response differed from one patient to another, both with respect to the number and quantity of antigens precipitated. See abstract.

9. Claims 1-3, 11, 14, 17, 20, 21, 23-26, 43, 65, 66, 68, 95,167-171, 173, 175, 178, and 199-203 are rejected under 35 U.S.C. 102(b) as being anticipated by Romain et al (Infect. Immun. Feb. 1993. 6192): 742-750).

Romain et al relate to the biochemical characterization of a complex of antigens which interact with antibodies present in serum of guinea pigs immunized with BCG. Romain et al teach that in order to identify mycobacterial molecules which are dominant antigens during immunization with living bacteria, a two-step selection method was used. Two groups of guinea pigs were immunized either with living or with heat-killed BCG. Sera were then colleted and used to select and counterselect antigens present in BCG culture filtrates. Each major fraction eluted from a series of high-pressure liquid chromatography columns (gle filtration, DEAE, and reverse-phase chromatography) was run on SDS-PAGE and transferred on polyvinylidene difflouride sheets. The molecules present on twin immunoblots were stained with antibodies raised in guinea

pigs immunized either with living or with heat-killed BCG. Cross-reactive antigens stained in twin immunoblots were eliminated. Major antigens interacting with antibodies raised after immunization only with living bacteria were further purified. See complete abstract.

10. Claims 1-3, 11, 14, 17, 20-22, 24-26, and 199-203 are rejected under 35 U.S.C. 102(b) as being anticipated by Kronberg et al (APMIS 100: 175-182, 1992).

Kronberg discloses the separation and identification of antigenic components of immune complexes in CF sputum using SDS-PAGE and immunoblotting. Immune complexes were precipitated with PEG and then analyzed by SDS-PAGE before transfer to nitrocellulose. See abstract. Those transferred were probed with, among others, pooled sera from patients chronically infected with P.aeruginosa. Kronberg et al demonstrate the existence of immune complexes consisting of LPS and anti-LPs antibodies. See abstract and whole document.

Claim Objections

11. Claim 43 is objected to because of the following informalities:

In claim 43, lines 1 through part 2 contain several errors upon amendment. The first line should be amended to delete the article "A" after 'wherein the' and the word 'comprising' in line 3 should be changed to 'comprise'. Appropriate correction is required.

In claim 43, line 2 of part (I) the words 'suffers' should be deleted and the words "the" and "having" after the insertions should also be deleted.

In claim 43, line 2 of part (II) the word "the" following the insertion 'an' should be deleted.

Appropriate correction is required.

Status of claims:

No claims are allowed. The purpose of many immunological testing methods which have been known in the art for 30-some years is to identify antigenic molecules which are then tested to determine whether they can stimulate an immune response. This is often performed by immunizing an animal and testing to determine whether antibodies are raised against the particular immunogen. The instant claims appear to define nothing more than a standard immunoassay or immunoaffinity process.

Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15,1989). The Group 1645 Fax number is 571-273-8300 which is able to receive transmissions 24 hours/day, 7 days/week.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Thursday from 8:00 AM-6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi, can be reached on (571) 272-0956.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.

/Jennifer E. Graser/
Primary Examiner, Art Unit 1645

3/22/10